

REMARKS

This Amendment and Response to Office Action responds to the Office Action mailed on January 5, 2005 in the above-identified patent application. Claims 19-41 were pending in this application. Claims 1-18 were cancelled by previous amendment. Claims 24, 35 and 39-41 are cancelled by this amendment. Claims 19-23, 25-34, 36-38 have been amended to further define technical features of the present invention. Support for amended claims is found in the Specification, for example in the section entitled "Objects of the Invention." No new matter has been added. Claim 19 is the sole independent claim.

In the Office Action claims 19-41 stand rejected under 35 U.S.C. 112, first paragraph and also stand rejected under 35 U.S.C. 112, second paragraph. Additionally, claims 19-41 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the corresponding claims of U.S. Patent No. 5,866,434 (the "*434 patent*").

The following remarks are believed to be fully responsive to the Office Action.

I. The "Written Description" Objection to Claims 39-41

Claims 39-41 stand rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement.

Although Applicants disagree with the examiner's basis for this rejection, as co-reactants were described in the published PCT application US 89/04859 incorporated by reference in this application (*see* Specification at 40:18-20) and were clearly understood by a skilled artisan at the time the specification was filed, in order to expedite prosecution, claims 39-41 have been cancelled. The rejection is thus rendered moot by this amendment.

II. The “Written Description” Objection to Claims 19-38

Applicants submit that claims 19-38 fully comply with the written description requirement. A skilled artisan will readily recognize what the term “substance” is meant to encompass and that Applicants were in possession of the claimed invention.

Although Applicants disagree with the Examiner’s rejection, in order to expedite prosecution, claim 19 has been amended to more clearly define what applicants regard as their invention. Currently amended claim 19 is directed to a “composition,” a regular term of art in the field of patents (Applicants note that “composition of matter” is one of the recognized statutory classes).

Furthermore, the term “composition” is literally described in the specification (*in haec verba*). “It is also an object of this invention to provide compositions and assays using graphitic nanotubes (fibrils) which can be labeled with compounds capable of being induced to luminesce.” (*Specification*, Objects of the Invention, at 20:19-22).

The Examiner’s attention is directed to MPEP §§ 2163 - 2163.07. The proper standard for determining whether an applicant has satisfied the “written description” requirement of the first paragraph of 35 USC § 112 is whether the applicant has conveyed with reasonable clarity to those skilled in the art that, as of the filing date of the application, that the applicant was in possession of the invention. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991).

Applicants submit the original specification adequately describes the claimed invention pursuant to the first paragraph of 35 USC 112, because one of ordinary skill in the art would

readily understand that Applicants had possession of the claimed composition. As stated in the MPEP:

An objective standard for determining compliance with the written description requirement is, “does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed”....

[MPEP 2163.02].

The examiner must have a reasonable basis to challenge the adequacy of the written description. Indeed, the examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *Wertheim*, 541 F.2d at 263, 191 USPQ at 97; MPEP 2163.04.

Further, claim 19 as amended is explicitly directed to enzyme co-factors selected from a group consisting of NADH, NADPH, NAD⁺, NADP⁺ or a derivative thereof. Accordingly, Applicants submit that the original specification adequately describes the claimed invention pursuant to the first paragraph of 35 USC 112.

Favorable reconsideration is earnestly solicited.

III. The “Enablement” Rejection of Claims 19-41

Claims 19-38 stand rejected under 35 U.S.C. 112, first paragraph (claims 19-41 were actually rejected, but claims 39-41 have been cancelled). The Examiner alleges that certain configurations of reactive components on the nanotube are required for the composition to be useful for the stated purpose of the invention.” Office Action, at page 3.

Applicants respectfully traverse.

There is no reasonable basis to assert that the claims be limited to “specific distances and types of attachments” as suggested in the Office Action mailed on June 17, 2004 at page 2. The fact that a claim may encompass some non working embodiments is not dispositive. The specification provides extensive disclosure of the claimed compositions and various methods used to prepare the claimed compositions. The chemical compositions in the preferred embodiments of the instant invention were actually reduced to practice as indicated by Examples 10 and 11 and production of the other compositions of the currently pending claims is fully within the purview of a skilled artisan. Every stage of the process is disclosed in great detail, therefore enabling a person of ordinary skill in the art to practice the claimed invention without undue experimentation.

Appellants submit that one of ordinary skill in the art would be able to practice the presently claimed subject matter in view of the specification and the prior art without undue experimentation. The test for enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 190 U.S.P.Q. 214 (CCPA 1976); MPEP § 2164.01. The fact that experimentation may be complex does not necessarily make it undue if those skilled in the art typically engage in such experimentation. *In re Certain Limited - Charge Cell Culture Microcarriers*, 221 U.S.P.Q. 1165, 1174 (Int’l Trade Comm’n 1983); *M.I.T. v. A.B. Fortia*, 227 U.S.P.Q. 428 (Fed. Cir. 1985); *In re Wands*, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988); MPEP § 2164.01.

Contrary to the Examiner’s suggestion, the specification need not provide examples or specific description of embodiments for the entire scope of the invention. Detailed procedures for making and using an invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention. MPEP §2164. A

patent does not teach, **and preferably omits**, what is well known in the art. *In re Buchner*, 18 U.S.P.Q.2d 1331, 1332 (Fed. Cir. 1991); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 221 U.S.P.Q. 481, 489 (Fed. Cir. 1984); MPEP § 2164.01. Even assuming, *arguendo*, that some compositions are non-functional for the stated purpose, it is not necessary for this approach to be successful in every case to satisfy the enablement requirement of 35 USC 112, first paragraph.

Applicants submit that one of ordinary skill in the art would be able to practice the claimed invention without undue experimentation in view of the teachings set forth in the specification. Favorable reconsideration is earnestly solicited.

IV. The Indefiniteness Rejection

Claims 19-38 stand rejected under 35 USC 112, second paragraph, as allegedly being indefinite.

Applicants submit that the terms in the claims are sufficiently clear and definitely to one of ordinary skill in the art in compliance with 35 USC 112, second paragraph.

(a) With respect to the term “substance”, claim 19 has been amended to recite a “composition”, a term which is literally described in the specification. The basis of the rejection is rendered moot by this amendment.

With respect to term “ECL co-reactant”, currently amended claim 19 explicitly recites enzyme co-factors selected from a group consisting of NADH, NADPH, NAD⁺, NADP⁺ or a derivative thereof.

Applicants urge the claims are sufficiently clear and definite to one of ordinary skill in the art when properly construed in view of the specification. Accordingly, this aspect of the rejection is improper and should be withdrawn.

(b) With respect to the assertion that for claim 19 “relative configuration of the components cannot be determined” – this assertion is neither supported by fact nor reasoning. Claim 19 explicitly recites a carbon nanotube having an ECL label and an enzyme co-factor attached thereto.

There is absolutely no reason from the disclosure in the specification or the current scientific literature to assert that “ECL label is attached inside the nanotube.” (Office Action, page 3) The specification teaches modifying the carbon nanotube with functional groups to allow for the attachment of the components. It is unclear what is the basis for the Examiner’s objection.

Accordingly, Applicants urge that this aspect of the rejection is improper and should be withdrawn.

(c) Claims 28 and 29 have been amended, as suggested by the Examiner. The rejection is rendered moot by the amendment.

(e) With respect to claims 37 and 38, the Examiner asserts that the claims are allegedly “incomplete for omitting essential steps, such omission amounting to a gap between the steps”. More specifically, the Examiner asserts that the “omitted steps are: (i) any requirement for a reaction between the ‘analyte’ and a component of the ‘composition’ which would trigger an ECL response and (ii) a step which correlates the ECL detection with the ‘presence or amount of analyte in the sample’” (Office Action, page 3).

One of ordinary skill in the art would readily understand the meaning and scope of claims 37 and 38 when properly construed in view of the specification. The Examiner is again reminded that breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971); MPEP Section 2173.04. Nevertheless, to further the prosecution of the application, Applicants have amended claim 37 to specify that “the presence of an analyte of interest causes oxidation or reduction of said enzyme co-factor.” The connection between the oxidation state of these NAD or NADP type cofactors and the ECL generated by the composition of the claims is clearly described in the specification. Accordingly, Applicants respectfully submit that claims 37 and 38 are sufficiently clear and definite to one of ordinary skill in the art in view of the specification. Therefore, this aspect of the rejection should be withdrawn.

V. The Double Patenting Rejection

Finally, claims 19-38 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-10 of US Patent No. 5,866,434 (the “’434 Patent”). In support of the rejection, the Examiner relies on the disclosure in the specification of the cited reference, *i.e.*, “as described at col. 49, line 63 – col. 50, line 10 of US 5,866,434.” (Office Action, page 5).

Determination for an obviousness type double patenting rejection must be based on the comparison of the currently pending claims to the previously issued claims (*In re Berg*, 46 U.S.P.Q.2d 1226 (Fed.Cir. 1998)). Applicants submit that the ‘434 Patent specification’s teachings cannot be used as prior art in an obviousness type double patenting analysis with the

'434 Patent claims since only the disclosure of the invention claimed in the '434 patent claims may be examined. *In re Vogel*, 422 F.2d 438, 441-42, 164 U.S.P.Q. 619, 622 (C.C.P.A. 1970).

The Examiner makes no allegation that the currently pending claims are by themselves obvious over claims of the '434 Patent. The Examiner did thus not meet the appropriate burden and, therefore, an obviousness type double patenting rejection is not warranted.

Further, amended claim 19 is explicitly directed to enzyme co-factors selected from a group consisting of NADH, NADPH, NAD⁺, NADP⁺ or a derivative thereof. The specific enzyme co-factors of claim 19, as amended, are not obvious over the claims of the '434 Patent, cited by the Examiner.

Accordingly, the rejection is improper and should be withdrawn.

CONCLUSION

In view of the comments and remarks herein, Applicants believe that each ground for rejection or objection made in the instant application has been successfully overcome and that all the pending claims are in condition for allowance. Withdrawal of the Examiner's rejections and objections, and allowance of the current application are respectfully requested.

The Examiner is invited to telephone the undersigned in order to resolve any issues that might arise and to promote the efficient examination of the current application.

No additional fees are believed to be necessary in connection with the filing of this Amendment. However, if any additional fees are required, the Commissioner is hereby

authorized to charge such fee(s), or credit any overpayments, to Deposit Account No. 50-0540.

Dated: May 5, 2005.

Respectfully submitted,
KRAMER LEVIN NAFTALIS & FRANKEL LLP
Attorneys for Applicants

By:

A handwritten signature in black ink, appearing to read 'Aaron Haleva', is written over a horizontal line.

Aaron S. Haleva
Reg. No. 44,733
Barry Evans
Reg. No. 22,802
1177 Avenue of the Americas
New York, NY 10036
Tel. (212) 715-7773
Fax (212) 715 9397